

General Hospital, Singapore; <sup>¶</sup>Dept. of Epidemiology and Preventive Med., Monash University, Australia; <sup>#</sup>Ctr. for Hlth.Economics, Monash University, Australia; <sup>††</sup>Monash Dept. of Clinical Epidemiology, Monash University, Australia

**Purpose:** All current international clinical guidelines recommend conservative non-pharmacological treatments, such as physical therapy, for hip osteoarthritis (OA). Physical therapy for hip OA is typically multimodal, with exercise, manual therapy, education/advice, and gait aids routinely employed worldwide. While there is limited support for some individual components, namely exercise and manual therapy, evidence about the efficacy of physical therapy management is inconclusive due to the lack of quality studies. Given the substantial contribution of both the placebo effect and the benefits associated with therapist contact during OA treatment, inclusion of a sham physical therapy control group would enable the impact of active physical therapy to be more accurately evaluated in such trials. Therefore, the primary aim of this study was to evaluate whether a 12-week multimodal physical therapy program, with components typical of international clinical practice, leads to greater improvements in pain and physical function compared to sham physical therapy.

**Methods:** In a randomized, assessor- and participant-blinded, placebo-controlled trial, volunteers with hip osteoarthritis were randomly assigned to receive either active or sham physical therapy. All participants received ten treatment sessions over 12 weeks with a physical therapist. Active treatment comprised a semi-standardized multimodal program including education/advice, manual therapy, home exercise and, if appropriate, provision of a gait aid. Sham treatment comprised inactive ultrasound and application of inert gel to the hip region. During the 24 weeks following treatment, the active group continued unsupervised home exercise while the sham group self-applied gel three times weekly. Primary outcomes were average overall pain using a visual analogue scale (0–100 mm) and physical function (0–68), measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at 13 and 36 following the completion of treatment. Secondary outcomes assessed physical impairments, physical performance, psychological status, quality-of-life and cost effectiveness. Statistical analyses were performed on an intention-to-treat basis using all randomized participants.

**Results:** One hundred and two participants were enrolled and 96 (94%) and 83 (81%) completed the week 13 and 36 follow-up measurements respectively. Baseline characteristics were similar between the two groups. There were no significant between-group differences in change in VAS pain (4.8 mm, 95% CI -4.6 to 14.3,  $p=0.32$ ) or WOMAC physical function (0.7 units, 95% CI -3.9 to 5.3,  $p=0.77$ ) at the 13 or 36 week time points. Observed between-group differences were smaller than the minimal clinically important differences, and the 95% confidence intervals indicated that the ranges of plausible between-group differences were unlikely to have included differences of any practical importance. Both groups showed significant and similar within-group improvements in pain and physical function at both time points. There were no between-group differences for changes in all except two secondary outcomes.

**Conclusions:** We found that a 12-week multimodal physical therapy treatment for hip OA, with components typical of current international

clinical practice, did not confer additional benefits for hip pain or function over a realistic sham treatment that controlled for therapist contact time, therapeutic environment and home treatment. However, both groups did show significant and clinically relevant within-group improvements following treatment. Given that hip OA patients not undergoing treatment show little improvements over similar time frames, the lack of between group differences in our study most likely reflects a large placebo and/or treatment effect from the therapeutic relationship between the physical therapist and the patient.

## 76

### IS THERE A DOSE RESPONSE RELATIONSHIP BETWEEN WEIGHT LOSS AND SYMPTOM IMPROVEMENT IN PERSONS WITH SYMPTOMATIC KNEE OSTEOARTHRITIS?

I. Atukorala <sup>†</sup>, J. Makovey <sup>‡</sup>, L. Lawler <sup>§</sup>, S. Messier <sup>||</sup>, K. Bennell <sup>¶</sup>, D.J. Hunter <sup>‡</sup>, <sup>†</sup>Univ. of Colombo, Colombo 8, Sri Lanka; <sup>‡</sup>Univ. of Sydney, Sydney, Australia; <sup>§</sup>Prima Hlth.Solutions Pty Ltd, Sydney, Australia; <sup>||</sup>Wake Forest Univ., Winston-Salem, NC, USA; <sup>¶</sup>Univ. of Melbourne, Melbourne, Australia

**Purpose:** It has been established that weight reduction has the ability to decrease pain and disability in knee osteoarthritis (OA). A greater weight reduction is likely to cause incremental improvement in symptoms and function by reducing joint loading but has not been previously investigated. Therefore, this study examined the dose-response relationship between the magnitude of weight reduction and improvement in pain and functional outcome.

**Methods:** Consecutive participants with knee OA enrolled in a weight loss programme, "Healthy weight for life" were selected. All participants fulfilled the American College of Rheumatologists criteria for classification of knee osteoarthritis. This program is a structured remotely delivered 18 week knee and hip OA disease management program that systematically integrates intensive weight loss as part of its tailored interventions. This programme was conducted with the aim of a 7–10% loss of body weight by dietary intervention over 18 weeks. The participants were provided online and written healthy eating advice and lifestyle education and tools together with targeted telephone motivation and support. The dietary habits were changed over 3 phases: phase 1 - motivational weight loss utilizing low calorie diet meal replacement, with controlled portions, and free foods for 6 weeks; phase 2 - consolidation weight loss for 6 weeks and phase 3 - short term weight maintenance. All participants in this cohort received the same strength / balance / mobility exercise tools, instruction, support and encouragement.

All participants were assessed at baseline, 6 weeks and 18 weeks for body weight and Knee Injury and Osteoarthritis Outcome Score (KOOS). The dose-response relationship between weight-change category (>10%, 7.6–10%, 5.1–7.5%, 2.5–5.0% and <2.5% weight loss) and change in the KOOS scores was assessed using repeated measures ANCOVA and controlled for baseline age, BMI, baseline KOOS and gender. The weight loss categories were based on the IDEA trial goal ( $\geq 10\%$ ), the weight loss goal of the diet groups in the ADAPT study (5%) and the weight loss typically achieved in an exercise only cohort of older adults with knee OA (<5%).

Dose response of weight change with the change in pain and function in study population

	Change in KOOS Pain Score		Change in KOOS Function score		Change in KOOS Symptom score		Change in KOOS Sport and Recreation score		Change in KOOS Quality of Life Score	
	B (CI)	P	B (CI)	P	B (CI)	P	B (CI)	P	B (CI)	P
% Weight Change Continues	1.52 (1.00–2.04)	0.000	1.95 (1.38–2.52)	0.000	1.58 (1.04–2.11)	0.11	5.13 (2.45–7.81)	0.000	0.73 (0.51–0.96)	0.000
% Weight Change Categories										
>10	9.8 (6.3–13.5)	0.000	9.6 (6.1–13.2)	0.000	8.5 (4.5–12.1)	0.000	10.78 (5.2–16.3)	0.000	10.7 (6.5–14.8)	0.000
7.6–10	6.6 (2.9–10.3)	0.001	6.1 (2.4–9.7)	0.001	3.8 (0.2–7.5)	0.041	6.6 (0.9–12.3)	0.023	6.6 (2.3–10.8)	0.002
5.1–7.5	5.6 (1.9–9.3)	0.003	4.9 (1.3–8.5)	0.007	4.3 (0.7–8.0)	0.021	6.2 (0.5–11.9)	0.034	7.1 (2.8–11.3)	0.001
2.5–5	2.5 (-1.3–6.3)	0.205	0.5 (-3.3–4.2)	0.800	0.8 (-3.0–4.7)	0.667	2.3 (-3.6–8.3)	0.443	4.0 (-0.45–8.4)	0.078
<2.5	0		0		0		0		0	

\* Data is presented as regression coefficients (B) with confidence intervals (CI). Change in KOOS factors were entered as dependent variables. Regression models were adjusted for age, gender, baseline weight, height and KOOS measures.

\* Category of weight loss of <2.5 was entered as a reference variable.

**Results:** 1383 (70.9% females) persons were enrolled in this study. Mean age, height and weight was 64 years (SD  $\pm$  8.7), 1.66m (SD  $\pm$  0.09) and 95.12 kg (SD  $\pm$  17.2) respectively. The mean body mass index (BMI) was 34.4 (SD  $\pm$  5.2) with 81.7% of participants being obese at baseline. The mean KOOS pain and function scores were 56.3 (SD  $\pm$  16.8) and 59.5 (SD  $\pm$  18.3) respectively at baseline.

1303 (94.2%) of participants had a  $>2.5\%$  reduction in body weight. The number (%) of participants according to percentage weight loss categories were as follows: less than 2.5% = 79 (5.7%); 2.6–5% = 223 (16.1%); 5.1–7.5% = 332 (24.0%); 7.6–10% = 317 (22.9%) and  $>10\%$  = 431 (31.2%). Participants in weight loss categories did not differ on gender, age or baseline KOOS measures. There was a significant dose-response relationship to percentage of weight change across all weight change categories. The dose-response relationship was seen in all KOOS scores assessed, namely pain, function, symptoms, sport and recreation and quality of life scores on regression analysis. The group with the largest amount of weight loss ( $\geq 10\%$ ) showed the most improvement in the pain, function and all the other characteristics assessed (Table 1). The non-weight loss interventions (eg. strength / balance / mobility exercise, personal support, pain management strategies etc.) were consistent across the cohort and would have also contributed to the improvement seen in the low weight loss group.

**Conclusions:** There is a strong dose response relationship between the percentage weight loss and the improvement in knee pain, function, symptoms, sport/recreation and quality of life. The approximately 40% improvement in symptoms in those losing 10% of their body weight is consistent with the recent pivotal IDEA trial. This study confirms the dose-response benefit of weight loss as a therapeutic intervention in knee osteoarthritis and demonstrates the effectiveness of disseminating and implementing a weight loss intervention in a community based setting.

## 77

### LAND-BASED EXERCISE FOR OSTEOARTHRITIS OF THE HIP: UPDATED SYSTEMATIC REVIEW AND META-ANALYSIS.

M. Fransen<sup>†</sup>, S. McConnell<sup>‡</sup>, G. Hernandez-Molina<sup>§</sup>, S. Reichenbach<sup>||</sup>.  
<sup>†</sup>Univ. of Sydney, Lidcombe, Australia; <sup>‡</sup>St Joseph's Hlth.Care Ctr., Toronto, ON, Canada; <sup>§</sup>Inst. Natl. de Ciencias Medicas y Nutricion Salvador Zubiran, Mexico City, Mexico; <sup>||</sup>Univ. Hosp., Bern, Switzerland

**Purpose:** To determine whether land-based therapeutic exercise is beneficial for people with hip OA in terms of reduced joint pain and improved physical function or quality of life.

**Methods:** A systematic review and meta-analysis. Five databases were searched from inception up until February 2013. All randomised controlled trials (RCTs) recruiting people with hip OA and comparing some form of land-based therapeutic exercise (as opposed to exercises conducted in the water) with a non-exercise group were included. Programmes could be designed and supervised by physiotherapists or other professionals, or provided as a home program with minimal monitoring. Pre-surgery (total hip replacement) programs were excluded. The comparator could be active (any non-exercise intervention) or placebo (no treatment or waiting list) group. Studies that compared one type of exercise programme to another exercise programme, provided an exercise programme to all treatment allocations (and evaluated the added benefit of an electrophysical agent or hydrotherapy), compared exercise with manual therapy and those comparing programmes of varying intensities, were excluded.

Four reviewers independently selected studies for inclusion. Disagreements were resolved through consensus. Two reviewers independently extracted data and assessed methodological quality. All analyses were conducted on continuous outcomes. Results were pooled using standardised mean differences (SMD) to calculate treatment effect sizes from the end of treatment scores and related standard deviation (SD) scores, where possible. Outcomes pooled using SMD were re-expressed as absolute mean difference using a representative control group (high weighting in pooled analyses) baseline SD.

**Results:** A total of ten RCTs were identified, seven considered to demonstrate a low risk of bias. One of the ten RCTs was only reported as a conference abstract and did not provide sufficient data for the evaluation of bias risk.

High quality evidence from nine trials (549 participants) indicated exercise reduces pain (SMD -0.38, 95% CI -0.20 to -0.55) and improves physical function (SMD -0.38, 95% CI -0.05 to -0.54) immediately after

treatment. Pain and physical function was estimated to be 40 points on a 0 to 100 point scale (0 is no pain or loss of physical function) in the control group; exercise reduced pain by an equivalent of 8 points (4 to 11 points) and improved physical function by an equivalent to 7 points (1 to 12 points).

The reduction in pain was sustained at least three to six months after ceasing monitored treatment (five RCTs, 391 participants): pain (SMD -0.38, 95% CI -0.18 to -0.58). This translates to a sustained reduction in pain intensity of 8 points (4 to 12 points) compared to the control group (0 to 100 scale). The improvement in physical function was also sustained (five RCTs, 367 participants): physical function (SMD -0.37, 95% CI -0.16 to -0.57) which translates to a mean improvement of 7 (4 to 13) points compared to the control group.

There was limited evidence from three studies (183 participants) of no benefit of exercise in terms of quality of life (SMD -0.10, 95% CI 0.19 to -0.40).

Only five of the ten RCTs exclusively recruited people with symptomatic hip OA (419 participants). There was no significant difference in pain or physical function outcomes compared with five studies recruiting participants with hip or knee OA (130 participants).

**Conclusions:** Pooling the results of these nine RCTs demonstrated that land-based therapeutic exercise programs can reduce pain and improve physical function among people with symptomatic hip osteoarthritis.

## 78

### EXERCISE THERAPY, MANUAL THERAPY, OR BOTH, FOR MANAGEMENT OF OSTEOARTHRITIS OF THE HIP OR KNEE: 2-YEAR FOLLOW-UP OF A RANDOMIZED CLINICAL TRIAL

J.H. Abbott<sup>†</sup>, C. Chapple<sup>‡</sup>, D. Pinto<sup>‡</sup>, A.A. Wright<sup>§</sup>, S.L. de la Barra<sup>†</sup>, G.D. Baxter<sup>†</sup>, J.-C. Theis<sup>†</sup>, f. the MOA Trial Team<sup>†</sup>. <sup>†</sup>Univ. of Otago, Dunedin, New Zealand; <sup>‡</sup>Northwestern Univ., Chicago, IL, USA; <sup>§</sup>High Point Univ., High Point, NC, USA

**Purpose:** There is evidence supporting the effectiveness of both exercise therapy and manual therapy for hip and knee osteoarthritis (OA), but few clinical trials report their incremental effectiveness compared with usual medical care, and most report only short-term follow-up.

**Methods:** This was a randomized controlled trial with 2-year follow-up. Adults meeting the American College of Rheumatology criteria for hip or knee OA were randomly allocated to receive the following interventions in addition to usual care: a) exercise therapy; b) manual therapy; c) combined exercise therapy and manual therapy; or d) no trial intervention (i.e. usual medical care only). Groups a-c were provided 10 treatment sessions, including 7 sessions in the first 9 weeks, plus 2 booster sessions at 4 months and 1 at 13 months. Participants were reassessed at 2 years, blind to group allocation. We report treatment effects on the Western Ontario and McMaster (WOMAC) osteoarthritis index (24 questions, 0-10 scale, total range 0-240), quality-adjusted life years, and physical performance measures (timed up-and-go, 40m fast-paced walk, 30 second sit-to-stand).

**Results:** Of 206 participants recruited, 186 (90.3%) were retained at 2 years follow-up. Mean age at baseline was 66 years (range 37 to 92), and mean WOMAC was 100.8 (SD 53.8). Missing data were replaced using multiple imputation. Intention-to-treat analysis of covariance (ANCOVA) showed WOMAC score changes at 2 years were superior for all three intervention groups compared with the usual care group (2-sided  $p < 0.05$ ). Participants receiving exercise therapy in addition to usual care showed gains of 31.7 WOMAC points (95% CI 10.0, 53.3), for an effect size of 0.57 (Cohen's d; 95% CI 0.17, .97). Gains for participants receiving manual therapy were 30.1 (8.9, 51.3) for an effect size of 0.55 (.16, .94). Gains for participants receiving combined exercise therapy and manual therapy in addition to usual care did not meet our a priori threshold for clinical significance, at 26.2 (6.1, 46.3) WOMAC points, but did result in a clinically significant effect size of 0.52 (.11, .91). Exercise therapy in addition to usual care resulted in significant QALY gains compared with usual care only (.05 QALYs,  $p = .002$ ), but manual therapy or combined therapy did not (both  $p > .05$ ). The exercise therapy group showed greater mean changes on most physical performance tests than did the other groups.

**Conclusions:** Both exercise physiotherapy and manual physiotherapy provided incremental benefit over usual care alone at 2 years follow-up. QALY gains and physical performance test outcomes significantly favoured the exercise therapy group.